



October 3, 2011

Jerry Menikoff, M.D., J.D. Director  
Office for Human Research Protections  
Department of Health and Human Services  
1101 Wootton Parkway, Suite 200  
Rockville, MD 20852

Office of the Provost

Randolph W. Hall, Ph.D.  
Vice President, Research

**SUBJECT:** USC Response to Advanced Notice of Proposed Rulemaking for Revision to Common Rule

Dear Dr. Menikoff,

Thank you for providing the opportunity for University of Southern California to comment on proposed changes to the Common Rule. As Vice President for Research, I am the Institutional Official for human subjects research, and therefore responsible for ensuring the protection of human subjects who participate in research studies at the university. The University has an exemplary record in human subject protection.

While I compliment the effort of HHS to take a fresh look at the Common Rule, I am deeply concerned that the proposed changes will hinder America's ability to conduct research while providing no benefits to human subjects. Thus, I believe that many of the proposed changes run counter to President Obama's executive order that federal agencies ensure that regulations protect our safety, health and environment while promoting economic growth. To be competitive with other nations, America's research institutions need greater flexibility, not increased regulation. Specifically:

- Proposed changes will render obsolete electronic submission systems, existing IRB forms and institutional policies. Other costly changes include re-education of the research community, new data security standards, and new legal agreements among collaborating institutions. The changes will force the university to waste resources that could be better used to increase student access to higher education.
- Placing all research, whether funded or not, under the jurisdiction of OHRP will harm our ability to conduct innovative research and educate students. Low-risk student research and minimal-risk unfunded research do not need further regulation.
- Highly successful flexibility efforts employed by institutions that have "unchecked the box" will all be eliminated. Institutions leading this effort include University of Michigan, University of Minnesota, USC and Stanford.

I also recommend that HHS consider the recommendations of the National Academies Study of Research Universities, which will soon issue recommendations on how to strengthen America's universities through reduction in regulation.

Sincerely,

Randolph W. Hall,  
Vice President of Research  
Attachments: (1)

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